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age age was 69.2 years (SD=10.1) and the proportion of men was slightly higher (54.4%). The hypoglycemia incidence was higher in patients with than without renal insufficiency (10.8% vs. 3.6%; p<0.001). Similarly, the metabolic acidosis incidence was higher in patients with than without renal insufficiency (1.9% vs. 0.9%; p<0.001). Renal insufficiency in diabetic patients was associated with increased hypoglycemia [OR: 3.3 (95% CI: 2.8 – 3.9)], and metabolic acidosis [OR: 2.2 (95% CI: 1.5 – 3.2)]. **CONCLUSIONS:** A significant proportion of diabetic patients with chronic renal failure experienced hypoglycemia or metabolic acidosis. Treatment strategies for these patients that minimize the risk of these complications should be considered.

PDB4

CONDUCT OUTCOMES RESEARCH IN CHINA - ADDRESSING CHALLENGES IN DATA QUALITY CONTROL

Zhang D[1], Ji L[2], Hu D[2], Zeng Y[3], Zhang Z[3]
[1]VitalStrategic Research Institute, Berwyn, PA, USA, [2]Peking University People's Hospital, Beijing, China, [3]VitalStrategic Research Institute, Shanghai, Shanghai, China

OBJECTIVES: In China, an estimated 90 million adults are diabetic. An out-patient clinic physician in a comprehensive hospital sees an average of 50 patients per day. Patients but not physicians maintain the medical records. Investigators are not used to electronic data acquiring systems. All these factors present challenges for conducting quality outcomes research. We recently conducted "Nationwide Assessment of Cardiovascular Risk Factors in Chinese Patients with Type 2 Diabetes", which was aimed to enroll 25000 non-institutional patients nation-wide. In order to ensure high quality and efficiency of the study, a multifaceted data quality control process was implemented and evaluated. **METHODS:** For enrolled patients who signed informed consent form, investigators were first required to report the original patient information on a "Patient Record Form" which served as source documents, and subsequently to enter the data into a web-based electronic data capture system (VitalEDC, VSRI), which performs instantaneous edit checks and generates real time data query. All investigational sites received frequent onsite monitoring and auditing when frequent data query occurred or when 50% enrollment achieved. Additionally, a 10% of the patient records at each site were randomly selected for a remote source document verification (rSDV). **RESULTS:** A total of 734 investigators from 103 hospitals across 6 regions of China participated in this study, and 25817 patients were enrolled within 8 months. Among enrolled patients, 100% the data were retrieved, 4,590,00 data records were evaluated, over 3000 unique queries were generated, only 1.5% (377 out of 25,817) of the patients' records were excluded from analyses due to unexplainable queries of pre-defined key information. **CONCLUSIONS:** The large sheer volume and rising epidemic of cardiometabolic and other chronic diseases demand well controlled epidemiological and comparative effectiveness research in China. Despite challenges, multifaceted measures of quality control could yield relatively satisfactory outcomes.

PDB5

EFFICACY AND SAFETY OF LIRAGLUTIDE 1.2MG AND EXENATIDE 10MCG TWICE DAILY IN TYPE 2 DIABETES MELLITUS: A SYSTEMTIC REVIEW AND META-ANALYSIS

Ye Q[1], Ploug UJ[2]
[1]Novo Nordisk (China) Pharmaceuticals Co., Ltd., Beijing, China, [2]Novo Nordisk A/S, Søborg, Denmark

OBJECTIVES: To systematically examine the efficacy and safety of liraglutide 1.2mg once-daily and exenatide 10mcg twice daily indirectly using meta-analysis of randomized controlled trials (RCTs) involving a common comparator. **METHODS:** A systematic review of the literature and meta-analysis was conducted. PUBMED and MEDLINE (January 2000 – July 2011) were searched to identify English-language randomized trials. Keywords included type 2 diabetes, liraglutide or exenatide, and randomized controlled trials. Inclusion criteria were RCTs >12 weeks in duration, type 2 diabetes patients≥18 years old, involving liraglutide 1.2mg once daily or exenatide 10mcg twice daily. Meta-analysis was conducted for the following outcomes: change from baseline in HbA1c, systolic blood pressure, weight and the number of hypoglycemic episodes. Data were extracted and tabulated by two independent reviewers and differences were solved by consensus. 41 RCTs were identified and 16 RCTs were included for further review. Only 10 RCTs with placebo as common comparators had sufficient information and were included in the analysis. Weighted mean differences (WMD) and their 95% confidence intervals were calculated as appropriate. STATA 11.0 (StataCorp, College Station, Tex) was used to perform the meta-analysis. **RESULTS:** Liraglutide 1.2mg once daily reduced HbA1c 1.10% more than placebo (p<0.001); exenatide 10mcg twice daily reduced HbA1c 0.60% more than placebo, but not statistically significant (p=0.723); liraglutide 1.2mg reduced weight 0.18kg more than placebo (p=0.060),and exenatide reduced weight 0.53kg more than placebo (p=0.084); The rate of moderate hypoglycemia associated with liraglutide 1.2mg was 2.93% in comparison to placebo; The rate of moderate hypoglycemia associated with exenatide 10mcg was 9.22% in comparison to placebo. **CONCLUSIONS:** Indirect comparison of liraglutide 1.2mg once daily and exenatide 10mcg twice daily suggest that in comparison to exenatide 10mcg, liraglutide 1.2mg provided greater improvement in HbA1c, with fewer hypoglycemia episodes.

PDB6

ANGIOTENSIN RECEPTOR BLOCKERS AND RISK OF CARDIOVASCULAR DEATH IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

Phung OJ, Sakharkar PR, Law AV
College of Pharmacy, Western University of Health Sciences, Pomona, CA, USA

OBJECTIVES: Angiotensin Receptor Blockers (ARBs) are indicated for the prevention and treatment of kidney disease in patients with Type 2 Diabetes Mellitus (T2DM), with established efficacy for nephropathy outcomes. Randomized Controlled Trials (RCTs) have also shown the benefit of using ARBs on cardiovascular outcomes in patients with T2DM. Results from the ROADMAP trial raised concerns of increased risk of cardiovascular death with olmesartan. Currently available ARBs differ in terms of potency and surmountable versus insurmountable blockade; therefore, not all of them provide the same benefits and harms. In the absence of published direct comparative studies, however, an indirect comparison among these agents is necessary to inform clinical decision making. **METHODS:** A systematic literature search was conducted in PubMed and Cochrane Central Register of Controlled Trials through September 2011 for RCTs evaluating ARBs in patients with T2DM. Outcomes of interest were cardiovascular death, all-cause mortality, and cardiovascular morbidity and mortality. Outcomes were initially pooled using standard random-effects methods producing odds ratios (OR) and 95% confidence intervals (CI). Adjusted indirect comparisons between agents using pooled estimates were then performed using Song's method when a common comparator was available, typically a placebo. **RESULTS:** A total of 10,833 patients from 7 RCTs were analyzed. Compared to olmesartan, candesartan offered statistically significant protection against cardiovascular death (OR 0.14, 95%CI 0.03 - 0.72), while irbesartan trended towards protection (OR 0.22, 95%CI 0.05 - 1.02). No significant difference was found between candesartan and irbesartan in cardiovascular death (OR 0.64, 95%CI 0.31 to 1.34). No significant differences were found between any agents for all-cause mortality or cardiovascular morbidity or mortality. **CONCLUSIONS:** Differences in outcomes may exist between ARBs in patients with T2DM, so head-to-head clinical trials are required to confirm the findings of this adjusted indirect comparison analysis.

PDB7

EFFICACY AND SAFETY OF LIRAGLUTIDE 1.2MG ONCE DAILY IN TYPE 2 DIABETES MELLITUS: A SYSTEMATIC REVIEW AND META-ANALYSIS

Ye Q[1], Ploug UJ[2]
[1]Novo Nordisk (China) Pharmaceuticals Co., Ltd., Beijing, China, [2]Novo Nordisk A/S, Søborg, Denmark

OBJECTIVES: Comparing the efficacy and safety of liraglutide 1.2mg once daily with other hypoglycemic agents in adults with type 2 diabetes through systematic review and meta-analysis of randomized controlled trials. **METHODS:** A systematic review of the literature and meta-analysis was conducted. PUBMED and MEDLINE (Jan 2000 – July 2011) were searched to identify English-language randomized control trials. Keywords included: type 2 diabetes, liraglutide, and randomized controlled trials. Inclusion criteria were: RCTs >12 weeks in duration, type 2 diabetes patients ≥18 years old, comparing liraglutide 1.2mg once daily with placebo or other active diabetic medications. Meta-analysis was conducted for the following outcomes: change from baseline in HbA1c, systolic blood pressure and weight as well as the number of hypoglycemic episodes. Two reviewers independently assessed trials for inclusion and extracted data. Differences were solved by consensus. 41 RCTs were identified and 5 RCTs met the inclusion criteria. The comparators were rosiglitazone, glimepiride, placebo and sitagliptin, and were collectively defined as the "comparators". HbA1c, weight and systolic blood pressure were analyzed as weighted mean differences (WMD), and the number of hypoglycemic episodes as relative risks (RR). STATA 11.0 (StataCorp, College Station, Tex) was used to perform the meta-analysis. **RESULTS:** In comparison to the "comparator group", patients receiving liraglutide 1.2mg reduced HbA1c by 0.54% more (95% confidence interval, CI=-0.81 to -0.28, p<0.001); weight loss with liraglutide 1.2mg was 0.54 kg more than with comparators (95% CI=-0.72 to -0.36, p<0.001); liraglutide 1.2mg reduced systolic pressure 0.14mmHg more than the comparators (95% CI=-0.22 to -0.06, p<0.001); Hypoglycemia episodes were similar between liraglutide 1.2mg and the comparators (RR=0.86, 95%CI: 0.39 to 1.93, p=0.722). **CONCLUSIONS:** Liraglutide 1.2mg once daily is effective in glycemic control, has the advantage of promoting weight loss and reducing systolic blood pressure versus the comparators for treating type 2 diabetes.

PDB8

THE EFFECT OF DAPAGLIFLOZIN ON HEDIS PERFORMANCE MEASURES OF HBA1C IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

Bell K[1], Hardy E[2], De Bruin T[2], Wei L[1], Martin P[2], Ptaszynska A[1]
[1]Bristol-Myers Squibb Company, Princeton, NJ, USA, [2]AstraZeneca, Wilmington, DE, USA

OBJECTIVES: Healthcare Effectiveness Data and Information Set (HEDIS) measures are used to rate health plan performance; HEDIS quality of diabetes care measures include glycated hemoglobin (HbA1c) categories <7% or <8%, which define good control, and >9%, which defines poor control. Dapagliflozin, a sodium glucose cotransporter 2 inhibitor, is under clinical development for the treatment of type 2 diabetes mellitus (T2DM). We assessed the effect of dapagliflozin on achieving HbA1c outcomes by HEDIS categories. **METHODS:** Pooled data for dapagliflozin 10 mg/day (N=1066) vs placebo (N=1257) from nine 24-week, phase 3, randomized, placebo-controlled trials in patients with T2DM, including monotherapy (NCT00528372, NCT00736879) and add-on to metformin (NCT00528879, NCT00855166), glimepiride (NCT00680745), pioglitazone (NCT00683878), or insulin (NCT00673231), or initial combination with metformin (NCT00859898, NCT00643851) trials, were analyzed. Adjusted mean change in HbA1c from baseline to week 24 with dapagliflozin vs placebo was determined for patients with baseline HbA1c of <8%, ≥8% to<9%, and ≥9%. Additionally, the proportions of patients achieving HEDIS HbA1c categories of <7%, <8%, and >9% were assessed. **RESULTS:** Placebo-subtracted adjusted mean changes in HbA1c (95% CI) at 24 weeks with dapagliflozin were −0.45% (−0.56%, −0.33%), −0.62% (−0.75%, −0.48%), and −0.78% (−0.93%, −0.63%) for patients with baseline HbA1c <8%, ≥8% to<9%,